

Miracle-Ear®
Hearing Systems by Bausch & Lomb

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October 6, 2000

Honorable Donna Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Room 615F
Washington, D.C. 20201



Miracle-Ear Center
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Perryville, MO 63775
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Joyce A. Hill, R.N., BC-HIS
Hearing Aid Specialist
Missouri State License# 000816

A Franchisee owned and operated business

Dear Secretary Shalala,

The Food and Drug Administration may shortly propose changes to the way hearing aids are sold that could put me out of business and impede access to hearing care services for millions of our nations seniors.

I am a board certified, state-licensed hearing instrument specialist. For over 14 years, I have provide hearing health care services to hundreds of our state's rural hearing-impaired. I have a small business that employs six women with incomes to support themselves and assist their families. My staff and I regularly provide hearing health care in nursing homes, nutrition centers, rural service centers and patient homes. Our offices offer education, free service, free testing and support to the hearing impaired no matter what their insurance or medicaid reimbursement.

Presently, all three members of the hearing health care delivery team (hearing aid specialists, audiologists and physicians) are recognized as qualified entry points into the hearing health care delivery system. The rule FDA is advocating would allow audiologists—without any justification—to install themselves as the sole entry point to purchase of a hearing aid. In my area there are 5 audiologists for a rural gross population of 100,000 persons. Most work in conjunction with physicians so that the majority of their time is spent in clinical testing not fitting and follow up instruction. I have personally tried to recruit an audiologist to work in our company for several years without success. They prefer the clinical settings.

I am very concerned with reports that the Food and Drug Administration (FDA) has reportedly sent to you a proposal for revising the current regulations governing the dispensing of hearing aids in this country. The proposal would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. ***Please stop and carefully consider the impact that this proposed rule will have on the nation's hearing impaired and on the nation's small business hearing aid specialists.*** In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

Hearing impairment is a major health concern. Please don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.

I look forward to your response.

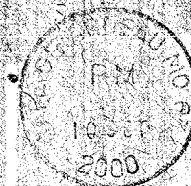
Sincerely yours,

Joyce A. Hill, R.N., BC- HIS
Miracle-Ear Franchisee

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